

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION**

**Hon. Renee M. Bumb**

**This Document Relates To:**

**Civ. No. 19-2875 (RMB/SAK)**

***All Actions***

**PLAINTIFFS' NOTICE OF VIDEOTAPED DEPOSITION OF TORRENT  
PHARMACEUTICALS LIMITED AND TORRENT PHARMA INC.  
PURSUANT TO FED. R. CIV. P. 30(b)(6) AND KELLY GEGENHEIMER**

**TO: Alexia Brancato  
Lindsey Foster  
Kirkland & Ellis, LLP  
601 Lexington Avenue,  
New York, NY 10022**

*Counsel for Defendants Torrent Pharmaceuticals LTD  
and Torrent Pharma Inc.*

PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30, and other applicable Rules, including the Local Civil Rules, and the applicable Orders of the Court, Plaintiffs, by and through their counsel, will take the videotaped of Kelly Gegenheimer, Vice President of Sales with Torrent Pharma Inc., as a designated corporate representative with regard to topic numbers 34-35, 37, and 41-45 as set forth in Exhibit A attached hereto and as a fact witness. The deposition will commence on **Wednesday September 25, 2024, at 9:30 A.M. Eastern Time**, and continue until completion, via remote deposition, in accordance with the Fact Witness Deposition Protocol and Case Management Order No. 20, filed on November 17, 2020 (Document 632).

The witness shall produce the documents requested at Exhibit B, attached hereto, at least 5 days in advance of this noticed deposition.

Pursuant to the meet and confer between the parties, a translator will not be provided.

**TAKING ATTORNEYS FOR PLAINTIFFS:**

Stacy Burrows  
Barton and Burrows, LLC  
5201 Johnson Dr., Ste. 110  
Mission, Kansas 66205  
[Stacy@bartonburrows.com](mailto:Stacy@bartonburrows.com)

The deposition will be taken before an officer authorized to administer oaths. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 16<sup>th</sup> day of September 2024.

**FOR PLAINTIFFS**

/s/ Stacy A. Burrows  
Stacy A. Burrows  
Barton and Burrows, LLC  
5201 Johnson Dr. Ste. 110  
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## **EXHIBIT A**

All topics reference information and documents known to, and/or in the possession, custody, or control, of Torrent, in the ordinary course of its business.

All references to Torrent include Torrent Pharmaceuticals Limited and Torrent Pharma Inc.

All references to the finished dose or Torrent's finished dose are defined to include the losartan finished dose manufactured, sold, or distributed by Torrent, which was manufactured in the facilities that manufactured losartan finished dose sold in the United States.

Each topic is to be interpreted consistent with the Court's oral rulings at the November 20, 2019 hearing on macro discovery issues; the Court's November 25, 2019 Order on macro discovery issues (Dkt. 303).

In accordance with the Court's Macro Discovery Order (ECF Doc No. 303), the terms "communications with any regulatory authority," "disclosures to regulatory authorities," and "filings with regulatory authorities" are limited to communications with the United States Food and Drug Administration, except insofar as the communications relate to regulatory inspection reports, warning letters, 483-like documents, responses to those documents, root cause analyses, and actual or potential nitrosamine contamination prior to July 2018, that were sent to or received from any foreign regulatory body during the designated relevant time period. All references to testing are defined to include testing capable of identifying the presence of nitrosamine contamination (i.e. NDMA, NDEA, NMBA), and/or detecting other carcinogens, general toxic impurities (including genotoxic impurities), and residual solvents, in connection with the manufacture and contents of Torrent finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)

- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

***Testing of Losartan API and Finished Dose***

1. The cause of the contamination of ZHP's valsartan API with nitrosamines including NDMA.
2. The root cause investigation for the nitrosamine impurities, including NDMA and NDEA in the ZHP API.
3. The testing performed by Torrent or its agents, to evaluate the purity and contents of ZHP's API.
4. The testing performed by Torrent or its agents, to evaluate the purity and contents of Torrent's finished dose.
5. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of ZHP's valsartan API.
6. The testing performed by any entity or person other than Torrent or its agents but known to Torrent, to evaluate the purity and contents of Torrent's finished dose.
7. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of ZHP's valsartan API.
8. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of Torrent's finished dose.
9. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of ZHP's valsartan API.
10. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of Torrent's finished dose.
11. Torrent's evaluation of the potential risks to the purity or contents of ZHP's API posed or caused by solvents used during the API manufacturing process.
12. Torrent's evaluation of the potential risks to the purity or contents of Torrent's finished dose posed or caused by solvents used during the finished dose manufacturing process.
13. The chromatogram and mass spectrometry or other results for all testing by ZHP or its agents of the solvents utilized in the manufacture of ZHP's valsartan API.
14. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the solvents utilized in the manufacture of Torrent's finished dose.
15. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than ZHP or its agents but known to Torrent, of the solvents utilized in the manufacture of ZHP's API.
16. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the solvents utilized in the manufacture of Torrent's finished dose.
17. 17. The chromatogram and mass spectrometry or other results for all testing by Torrent or its agents of the production equipment utilized in the manufacture of Torrent's finished dose.
18. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Torrent or its agents but known to Torrent, of the production equipment utilized in the manufacture of Torrent's finished dose.

19. The extent of the actual and potential nitrosamine contamination of Torrent's valsartan finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

***Quality Assurance and Quality Control Activities***

20. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of valsartan API.
21. Torrent's SOP's/policies/procedures intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Torrent's finished dose.
22. Torrent's application of cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Torrent's finished dose.
23. Deleted.

***Process Development***

24. Deleted.
25. The modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modification, and (3) the relationship between the modifications and the nitrosamine contamination of ZHP's valsartan API.
26. Any evaluation conducted by or on behalf of Torrent with regard to health or safety issues arising from the use of solvents, and the Tetrazole ring formation step, and in particular potential nitrosamine impurities, in the manufacturing process for ZHP's valsartan API.
27. Torrent's evaluation and knowledge of the risk of the creation of nitrosamines including NDMA and NDEA as a result of the manufacturing process for ZHP's valsartan API.
28. Torrent's evaluation and knowledge of the health risks of nitrosamines including NDMA and NDEA, including but not limited to as a contaminant of ZHP's valsartan API.
29. Deleted.

***Communications with Regulatory Agencies***

30. The communications with any regulatory authority, including but not limited to the FDA, with regard to the modifications with regard to the use of solvents, and the Tetrazole ring formation step, in the manufacturing process for ZHP's valsartan API.
31. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of ZHP's valsartan API with nitrosamines including NDMA and NDEA.
32. Torrent's disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Torrent's valsartan finished dose with nitrosamines including NDMA and NDEA.

***Torrent's Communications with API Manufacturers and Downstream Customers***

- 33. Torrent's oral and written communications with ZHP with regard to the content/purity/contamination of ZHP's valsartan API.
- 34. Torrent's oral and written communications with its losartan finished dose customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Torrent finished dose.
- 35. Torrent's oral and written statements (defined to include representations and warranties) to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Torrent's finished dose.
- 36. Torrent's product recall for valsartan finished dose, including who Torrent communicated with, how, about what, and the retention of recalled or sequestered valsartan finished dose.
- 37. All credits, indemnification, refunds, and/or penalties paid or provided by or to Torrent in connection with the nitrosamine contamination of losartan.

***Compliance with cGMPs***

- 38. Torrent's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Torrent's finished dose.
- 39. Deleted.

***Product Tracing***

- 40. Tracing of batches and lots of Torrent's losartan finished dose sold downstream and ultimately intended for use by consumers in the United States.
- 41. The pricing of Torrent's losartan finished dose that was ultimately sold in the United States (the parties to meet and confer to identify relevant documents).
- 42. The gross and net profits to Torrent from the sale of Torrent's losartan finished dose in the United States (the parties to meet and confer to identify relevant documents).
- 43. The quantity/units of Torrent's losartan finished dose sold in the United States (the parties to meet and confer to identify relevant documents).
- 44. The Torrent losartan finished dose sales and pricing data produced by you in this litigation (sample documents to be provided at least 30 days ahead of deposition during meet and confer process).

***Corporate Relationships***

- 45. Torrent's acquisitions and ownership of entities that purchased losartan API and sold losartan finished dose intended for use in the United States.

**EXHIBIT B**

**DOCUMENT REQUESTS**

1. The most recent resume/Curriculum Vitae and LinkedIn profile for Kelly Gegenheimer.
2. The complete production of Kelly Gegenheimer's relevant custodial documents, including those maintained on personal computers or electronic devices, to the extent not produced prior.

**CERTIFICATE OF SERVICE**

I, Stacy Burrows, hereby certify that on September 16, 2024, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Torrent Pharmaceuticals Limited and Torrent Pharma Inc., and Defendants' counsel, as listed above, via email.

DATED this 16<sup>th</sup> day of September 2024.

/s/ Stacy A. Burrows

Stacy A. Burrows

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